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August 29, 2013

By Facsimile (267) 299-5056

The Honorable Mitchell S. Goldberg
United States District Judge
United States District Court for the Eastern District of Pennsylvania
601 Market Street
Philadelphia, PA 19106

**Re: In re: Suboxone (Buprenorphine Hydrochloride and
Nalaxone) Antitrust Litig., No. 13-md-2445 (E.D. Pa.)**

Dear Judge Goldberg:

On behalf of the Defendants in the above-referenced matter,¹ I write in response to Plaintiffs' joint discovery requests dated August 22, 2013 ("Aug. 22 Ltr."). Plaintiffs ignore both the letter and spirit of this Court's decision to have significant discovery await its decision on the motions to dismiss. That ruling was designed to avoid imposing potentially needless burdens in light of Plaintiffs' own observation that "[t]his is not an easy case on the law." (Dkt. No. 45 at 33; *see id.* at 34-35.) Yet the bulk of Plaintiffs' requests are as broad—and as burdensome—as any that could be made in ordinary discovery. Such requests are inconsistent with the goal of finding discrete sets of documents that might be produced without any additional burden, because they had already been assembled, or were being assembled, for other purposes. Defendants further detail their objections below, and provide an alternative proposal more in keeping with Defendants' understanding of this Court's intention.

Plaintiffs' Requests. Plaintiffs have three basic claims, concerning: (1) the introduction and marketing of Suboxone film, (2) the negotiations with generic firms concerning Reckitt's Risk Evaluation and Mitigation Strategy ("REMS"), and (3) the Reckitt's citizen petition to the FDA. (*See* Aug. 22 Ltr. at 1-2.) Plaintiffs have now sought comprehensive discovery on all three claims.

¹ Both the Direct Purchaser Plaintiffs and the End-Payor Plaintiffs (collectively, "Plaintiffs") have named five entities as Defendants: Reckitt Benckiser Pharmaceuticals, Inc.; Reckitt Benckiser LLC; Reckitt Benckiser, Inc.; Reckitt Benckiser Healthcare (UK) Ltd.; and Reckitt Benckiser Group plc (collectively, "Defendants"). Reckitt Benckiser Pharmaceuticals admits that this Court has jurisdiction. The other four Defendants submit this letter by special appearance, without waiving any objections to jurisdiction. *See Ciolli v. Irvani*, 625 F. Supp. 2d 276, 290-91 (E.D. Pa. 2009).

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For example, relating to the product switching allegation, Plaintiffs seek any “[c]linical studies,” regardless of date, “pertaining to the safety *and/or efficacy* of Suboxone tablets and film,” which would include decades-old studies related to the earliest form of Suboxone. (Request 3 (emphasis added).) Plaintiffs also seek *all* of “Reckitt’s marketing, advertising, and/or promotional materials concerning Suboxone tablets and film” *for the last three years*, (Request 5), regardless of whether they are still current, or whether they compare the merits of film and tablets. Regarding the REMS program, Plaintiffs seek “[a]ll documents *relating to* Reckitt’s . . . REMS and an SSRS.” (Request 4 (emphasis added).) None of these sets of documents has been gathered for production, the vast majority are proprietary, and only some are relevant to the complaints before this Court.

The unlimited request for REMS documents alone demonstrates the heavy burden Defendants would face in responding. To comply with Rule 26(g) in responding to Plaintiffs’ REMS request, Defendants’ counsel would need to (1) interview Defendants’ employees to identify all potentially relevant custodians, (2) collect those custodian’s hard-copy documents and electronically stored information, (3) review each document for relevance and privilege (an especially daunting task where Plaintiffs allege that Defendants utilized counsel heavily in the REMS negotiations, *e.g.*, Direct Purchaser Compl. (Dkt. 47) at ¶ 106), and (4) process each document for production with an appropriate confidentiality designation, *after negotiating a protective order* (again, Plaintiffs themselves allege that portions of the REMS are non-public, *id.* at ¶ 107). Simply put, Plaintiffs’ *ipse dixit* that all REMS-related documents “could be produced easily” is false. (Aug. 22 Ltr. at 2.)

Plaintiffs’ requests for comprehensive (“all documents”) discovery on each of their claims are contrary to this Court’s intention in its ruling on discovery:

THE COURT: So you’re saying, at a minimum, one of -- and I’m oversimplifying your case, but you have three theories. You could prevail in defeating their motion to dismiss, hypothetically, on two out of your three theories, right?

MR. OPPER: Yes.

THE COURT: And that could be the shape of the case going forward with discovery?

MR. OPPER: Yes.

THE COURT: But you’ve lost, hypothetically, one of your theories, right? Why would it make sense to do discovery on all three? Why don’t

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you want to know what the shape of the case is so you know how to shape your discovery going forward?

(Dkt. No. 45 at 40-41 (emphasis added).) The Court's intuition was correct. Unless gathering and preparing those documents would impose no *additional* burden on Defendants, it does not make sense to permit Plaintiffs discovery on all of their theories prior to determining which theory, if any, is going forward.

Plaintiffs' requests are also—as Plaintiffs' letter implicitly acknowledges—unnecessary. Defendants' forthcoming Motions to Dismiss cannot as a matter of law “refer to facts that are outside Plaintiffs' complaint,” (Aug. 22 Ltr at 2), as defined by the rules, unless those facts are subject to judicial notice. A plaintiff is not permitted discovery to determine whether its complaint can survive a Rule 12(b)(6) motion. *See, e.g., Second Baptist Church of Leechburg v. Gilpin Twp., Pa.*, 118 F. App'x 615, 618 (3d Cir. 2004) (“The present dispute is before this Court on a Fed. R. Civ. P. 12(b)(6) motion to dismiss and the Church's arguments about what it would prove through discovery are thus irrelevant.”).

The breadth of Plaintiffs' discovery request proves that they cannot suggest any “discrete” categories of documents for production. (Aug. 22 Ltr. at 2.) Plaintiffs have ignored the Court's instruction to limit their requests to those documents “that can be produced readily,” (Dkt. No. 45 at 45), *i.e.*, without the need for a special collection.

Defendants' Proposal. Defendants therefore propose the following alternative. Defendants will produce:

1. Documents submitted to, or received from, the Food and Drug Administration in connection with Reckitt Benckiser Pharmaceuticals, Inc.'s Citizen's Petition.
2. The most recent, public version of each REMS or RiskMAP program related to Reckitt Benckiser Pharmaceuticals, Inc.'s distribution of Subutex, Suboxone Tablets, or Suboxone Film.
3. Documents containing Reckitt Benckiser Pharmaceuticals, Inc.'s most recent marketing materials for Suboxone Tablets and Suboxone Film, including, if available, documents comparing Suboxone Tablets to Suboxone Film.
4. Within thirty days of the completion of any document production in response to an ongoing or future governmental investigation,² Defendants shall (a) produce all relevant, non-confidential documents to Plaintiffs, (b) object to some or all of

² Whether a governmental investigation is ongoing is confidential by statute. *See generally* 15 U.S.C. § 1313(c).

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such production on the basis of relevance or the need for a protective order, and
(c) if Defendants believe that a protective order is required, provide to Plaintiffs a
proposed protective order to permit such production.

The first three categories of documents are, in fact, discrete and readily available, and
Defendants would be in a position to produce those three categories within 30 days of the
Court's order in response to these letters.

Defendants believe that this proposal will provide Plaintiffs with relevant material
while not requiring Defendants to undertake a burdensome investigation necessary to
certify that they are producing *all* documents relating to each of Plaintiffs' claims.
Defendants remain available to provide any additional information on this subject that the
Court may find useful.

Very truly yours,


Kevin D. McDonald

cc: Plaintiffs' Counsel (via email)

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Re: **In re Suboxone (Buprenorphine Hydrochloride and Nalaxone)**

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